

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

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ERFINDERGEMEINSCHAFT UROPEP  
GBR,

Plaintiff,

vs.

ELI LILLY AND COMPANY, and  
BROOKSHIRE BROTHERS, INC.,

Defendants.

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Court File No.: 2:15-cv-01202-WCB

**JURY TRIAL DEMANDED**

**DEFENDANT ELI LILLY & COMPANY'S OPPOSITION IN RESPONSE TO  
ERFINDERGEMEINSCHAFT UROPEP GBR'S MOTION IN LIMINE**

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Erfindergemeinschaft UroPep GbR's ("UroPep") six motions *in limine* should be denied. See Dkt. 205 (original motion) and Dkt. 207 (corrected motion).<sup>1</sup>

**I. UroPep's First Motion *In Limine* Should Be Denied: The Facts Behind The '124 Patent's Filing Are Relevant And Admissible**

UroPep's first motion seeks to exclude "evidence or argument suggesting that the timing of UroPep's patent application" and its attempt to draft claims allegedly covering Cialis® (tadalafil) were in any way improper. Dkt. 207 at 1. This motion must be denied. The timing of UroPep's filing of the application for the '124 Patent is a fact that will come into evidence in multiple ways (including via the face of the '124 Patent itself). UroPep's decision to seek a new patent to cover Cialis' BPH indication is directly relevant to UroPep's damages, inducement, and willful infringement claims, as well as Lilly's written description and enablement defenses.

The law squarely supports the admissibility of this evidence. Lilly was working on developing Cialis as a treatment for the signs and symptoms of BPH for years before any contact with UroPep. UroPep had previously sought broad patent coverage for its alleged invention during the earlier prosecution of the '124 Patent's parent application (the application for the "'061 Patent"). *E.g.*, Dkt. 191-3 at JX\_061\_FH0080 (claim 4). The Patent Office rejected those efforts on multiple grounds, including that they were unsupported by the patent's written description. Dkt. 191-4, at JX\_061\_FH0233, 236-237. The fact that UroPep only filed the application for the '124 Patent *after* Cialis received its BPH indication in a renewed attempt to seek broad coverage is "probative to the 35 U.S.C. § 112 inquiry," an issue of fact for the jury. *Rambus, Inc. v. Infineon Techs AG*, et al., 330 F. Supp. 2d 679, 694 n.22 (E.D. Va. 2004) (citing and discussing *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998)).

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<sup>1</sup> All citations will be to the corrected motion, Dkt. 207.

Moreover, the active compound in Cialis (tadalafil) is admittedly *not* identified in the ‘124 Patent’s specification. UroPep’s attempt to draft claims to try to cover the use of tadalafil because of Lilly’s successful pursuit of a BPH indication is additional evidence supporting Lilly’s written description defense. As the Federal Circuit explained in *Gentry Gallery*:

Finally, although not dispositive, because one can add claims to a pending application directed to adequately described subject matter, Sproule admitted at trial that he did not consider placing the controls outside the console until he became aware that some of Gentry’s competitors were so locating the recliner controls. Accordingly, when viewed in its entirety, the disclosure is limited to sofas in which the recliner control is located on the console.

134 F.3d at 1479.

This chain of events is also powerful evidence rebutting UroPep’s willful infringement claims. *See Gustafson, Inc. v. Intersys. Indus. Prods., Inc.*, 897 F.2d 508, 510–11 (Fed Cir. 1990) (reversing finding of willful infringement where product was on market prior to grant of patent) (citing cases). UroPep was repeatedly denied broad coverage during the prosecution of the parent application for the ‘124 Patent (the ‘061 Patent), and UroPep acknowledges that the ‘061 Patent does not cover any Cialis indication. There was no reason for Lilly to think that UroPep would ever assert any patent against it. If UroPep is permitted to claim that Lilly willfully infringed the ‘124 Patent,<sup>2</sup> Lilly must be permitted to present its defense.

UroPep’s filing of the application for the ‘124 Patent only after Lilly obtained Cialis’s BPH indication is also independently relevant to the proper measure of damages. *See* Lilly’s Motion to Exclude Certain of UroPep’s Damages and Technical Experts (Dkt. 175) at 8-11 and Reply (Dkt. 199, corrected at Dkt. 223) at 4-5. None of Lilly’s considerable investments can be (or is) attributable to Lilly’s knowledge of the patented technology. In the event that the jury

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<sup>2</sup> Lilly’s motion for summary judgment of no willful infringement is currently pending.  
 DEFENDANT’S OPPOSITION AND RESPONSE TO UROPEP’S MOTIONS IN LIMINE

weighs damages, it must understand that Cialis's BPH indication is not only solely attributable to Lilly's efforts, but that UroPep's embarked on its prosecution of the '124 Patent only after Lilly had been successful in those efforts.

Notably, UroPep cites no law regarding any of these issues in its sweeping exclusion request. Rather, UroPep makes misstatements or argues irrelevancies.

For example, UroPep bizarrely claims that Lilly does not "contend that the specification of the July 1997 application (and now the '124 patent) lacked a written description sufficient to cover tadalafil." Dkt. 207 at 1. Of course this is not true. The Court denied Lilly's prior motion for summary judgment of invalidity because it found that the *jury* should decide Lilly's written description defense. Dkt. 149 at 37 ("The Court is persuaded that what is disclosed in the specification, when viewed in light of what a person of ordinary skill in the art would have known at the time, is sufficient to at least raise a question of fact sufficient to take the written description issue to a jury"). A significant portion of the trial *is going to be about* the adequacy of the written description of the '124 Patent. UroPep cannot avoid reality (or this Court's rulings) by insisting upon the opposite.

UroPep also argues that "it did nothing improper by seeking a claim to cover tadalafil[.]" Dkt. 207 at 2 (citing the Court's "Unclean Hands Order," Dkt. 181 at 26) (further citation omitted). This assertion may be legally accurate, but it is irrelevant to the issues at hand. Lilly does not intend to argue that UroPep's actions were unlawful. Rather, Lilly expects to use the undisputed fact that UroPep only filed for the '124 Patent after it saw Lilly's success in adding a BPH indication to Cialis as evidence to support the Section 112 defenses, as well as to rebut UroPep's willful infringement and damages claims. The law expressly permits Lilly to do so. *See, e.g., Gentry Gallery*, 134 F.3d at 1479 (noting that, although it is acceptable under the law to

add claims to cover a product on the market, such actions can also be evidence supporting a written description defense).

UroPep cannot rewrite history or wish the law and the facts away. The law holds that UroPep's decision to file a new patent application after Cialis received its BPH indication in hopes of asserting a patent claim against Lilly is probative and relevant to the jury's determination of multiple issues that will be before it. UroPep's first motion *in limine* should be denied.

**II. UroPep's Second Motion *In Limine* Should Be Denied: The Prosecution History And Dr. Ückert's October 30, 2007 Declaration Are Relevant To Multiple Issues In The Lawsuit And Not Improperly Prejudicial**

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UroPep next asserts that Lilly should be barred from arguing that (1) Dr. Ückert's October 30, 2007 declaration (the "Ückert Declaration") "is in any way misleading or inaccurate" regarding the prior art and (2) there were "any purported irregularities in the prosecution of the '124 patent." Dkt. 207 at 2. These demands go too far and are not supported by UroPep's legal authority.<sup>3</sup>

The submission and contents of the Ückert Declaration during the prosecution of the '124 Patent's parent application (which issued as the '061 Patent) are facts; UroPep cannot run from them. The Ückert Declaration's discussion of the prior art reflects the views of a named inventor regarding both the prior art and the substance of UroPep's alleged invention(s). They are admissions by UroPep as to each. It is perfectly appropriate to cross examine Dr. Ückert and the other UroPep inventors as to the contents of the Ückert Declaration in order to support Lilly's invalidity defenses. *See, e.g., Gentry Gallery*, 134 F.3d at 1478–79 (noting the inventor's

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<sup>3</sup> UroPep does not identify what alleged "prosecution irregularities" are of concern aside from the Ückert Declaration, and Lilly has no way to know what (if anything) UroPep has in mind with regard to this vague reference. Additionally, to the extent that UroPep's motion is directed to striking Dr. Rotella's testimony (*see* Dkt. 207 at 2, citing Rotella Rpt., ¶¶ 156 – 162) it is untimely for the reasons set forth in Section III, below.

testimony regarding the substance of its invention was probative of the written description requirement). This examination can include not just challenging Dr. Ückert's views regarding the prior art, but also using Dr. Ückert's statements in his declaration to rebut UroPep's current claim that its patent specification is broad enough to encompass a method of "prophylaxis or treatment" of "benign prostatic hyperplasia" using Cialis.

For example, the following assertions by Dr. Ückert regarding the common specification of the '061 and '124 Patents are probative of whether UroPep truly had possession of subject matter of the '124 Patent's new (and unusual) claims:

- J Dr. Ückert's claim that multiple compounds disclosed in the '124 Patent but expressly **excluded** from the scope of the '124 Patent's claims "provid[e] superior activity in promoting prostate smooth muscle relaxation in comparison to other PDE inhibitors, and in comparison to other NO donor compounds (SNP)." [Ückert Declaration, ¶¶ 3 (listing compounds) and 14.]
- J Dr. Ückert's claim that "Example 2" (using sildenafil, another PDE5 inhibitor that is **excluded** from the claims of the '124 Patent) demonstrates "the unexpected superior performance of PDE 4 or PDE 5 inhibitors in this regard [*viz.*, "treating lower urinary tract symptomatology (LUTS) and benign prostatic hyperplasia (BPH)"], as demonstrated in the subject Application (Example 2)." [Ückert declaration, ¶ 8.]
- J Dr. Ückert's statement that other methods of stimulating NO activity in the prostate "are of minimal to no in the pharmacotherapy of the Benign Prostatic Syndrome (BPS) and Lower Urinary Tract Symptomatology (LUTS)," without an explanation of what additional benefit (if any) there is in inhibiting PDE4 or PDE5, aside from stimulation of NO activity, allegedly provides the therapeutic benefit. [Ückert Declaration, ¶ 9.]

Lilly should be permitted to cross-examine Dr. Ückert regarding his prior sworn statements. Dr. Ückert should not be permitted a free pass if he attempts to take a different position at trial.

Even if an opportunity for impeachment does not arise, however, the Ückert Declaration and the rest of the '124 Patent's prosecution history is still relevant to Lilly's invalidity defenses because they contain statements by UroPep regarding the contents and teachings of the prior art. *See, e.g., Purdue Pharma Products L.P. v. Par Pharmaceutical, Inc.*, 642 F.Supp.2d 329, 347

(D.Del. 2009) (noting that “[t]he prosecution history of the patents-in-suit is relevant to issues of both obviousness and inequitable conduct”). Indeed, the prosecution history consists of a series of admissions by UroPep regarding the prior art and provides important background for Lilly’s anticipation and obviousness defenses.

Similarly, although UroPep allows that Lilly’s experts can present “scientific disagreement[s]” with Dr. Ückert’s conclusions regarding the prior art in connection with Lilly’s defenses, those disagreements have no context unless Lilly’s experts can cite to Dr. Ückert’s (and UroPep’s) original positions in the first instance. Lilly also should be permitted to explore the differences between the positions now taken by UroPep in this lawsuit—including by UroPep’s experts—and positions taken in the prosecution history. The jury should be able to weigh UroPep’s (and Dr. Ückert’s) words today against the declaration Dr. Ückert submitted in 2007, before UroPep was in the midst of a lawsuit with Lilly.

Indeed, the evidence UroPep seeks to exclude is quintessential evidence for assessing the credibility not only of Dr. Ückert, but also of UroPep’s present case. Contrary to UroPep, this evidence can and will be introduced properly, within the limits of the law, and without wading into “the applicants’ absolute compliance with the internal rules of patent examination” (the issue in *Magnavision, Inc. v. The Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997)); accusing Dr. Ückert of being intentionally misleading (the issue in *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1329 (Fed. Cir. 2004)); or trying to build a record of “flawed prosecution arguments” or intentional misstatements (the issues in *Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc.*, 485 F. Supp. 2d 519, 535–36 (D. Del. 2007)), all cited by UroPep in Dkt. 207 at 3. The fact that the Ückert Declaration *could be* used in connection with claims not presently in the lawsuit (inequitable conduct or unclean hands) does not mean that it *cannot be* used to

support claims that are in the lawsuit (written description, enablement, anticipation, obviousness).

Finally, UroPep has not identified what additional “prosecution irregularities” it believes that Lilly may present at trial, and Lilly has no way to address issues that are not identified or briefed. The bottom line, however, is that the prosecution history reflects the facts regarding what occurred before the Patent Office. Lilly should be permitted to make proper use of the prosecution history, including the Ückert Declaration, where it is relevant to its claims and defenses. The solution to any concern that Lilly may overreach or try to use the prosecution history for some improper purpose is for UroPep to object to the specific line of questioning at trial. The Court should not enforce an unwarranted, blanket ban of Lilly’s use of evidence that is deeply probative of, and highly relevant to, multiple Lilly defenses.

### **III. UroPep’s Third Motion *In Limine* Should Be Denied: Dr. Rotella Followed The Court’s Order; He Did Not Contradict It**

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UroPep’s third motion *in limine*—directed to the opinions in two paragraphs of Dr. Rotella’s expert report (¶¶ 168 & 169)—contradicts the Court’s prior order on Lilly’s summary judgment motion and seeks to exclude opinions that are central to the issues that the Court found should be heard by a jury. Dkt. 207 at 3-4.

First, UroPep’s motion to strike Dr. Rotella’s testimony in these two paragraphs is untimely. The applicable Docket Control Order requires that “Motions to Strike Expert Testimony (including *Daubert* Motions)” must have been filed by January 17, 2017. Dkt. 166 at 3. UroPep did not file the present motion, which seeks to strike two paragraphs from Dr. Rotella’s report, until February 7, 2017.

Second, UroPep is wrong that these two paragraphs, which concern Dr. Rotella’s opinion that the ‘124 Patent’s applicants did not possess the full scope of PDE5 inhibitors, violate the

“law of the case.” Dkt. 207 at 3. “The law-of-the-case doctrine posits that when a court decides upon a rule of law, that decision should continue to govern the same issue in subsequent stages in the same case.” *Med. Ctr. Pharmacy v. Holder*, 634 F.3d 830, 834 (5th Cir. 2011) (quoting *United States v. Castillo*, 179 F.3d 321, 326 (5th Cir. 1999)) (further citations omitted).<sup>4</sup> The Court did not deny Lilly’s prior motion for summary judgment under Section 112 by making a legal determination; rather, the Court denied the motion because it found *issues of fact* for the jury to decide. Dkt. 149 at 37. The law of the case doctrine does not apply here; UroPep’s argument is premised on an inapposite legal principle.<sup>5</sup>

Third, contrary to UroPep, the two paragraphs of challenged opinions (Rotella Report, ¶¶ 168 & 169) are consistent with the Court’s prior findings. UroPep highlights that the Court found that “the written description issue does not turn on whether the patentees were in possession of the entire genus of PDE V inhibitors.” Dkt 207 at 4 (quoting Dkt. 149 at 30). True, but not relevant here. The Court’s determination that the written description issue “does not turn” on possession of the “entire genus of PDE V inhibitors” does not mean that evidence that the inventors did not describe the entire genus of PDE5 inhibitors must be ***excluded***. To the contrary, these opinions are important building blocks for the question that the Court did find to be determinative: “whether the disclosure in the specification shows that the inventors possessed the invention that administering an effective amount of a PDE5 inhibitor would treat BPH.” Dkt. 149 at 30. It certainly bears on this question whether, as an initial matter, the named inventors

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<sup>4</sup> The law of the case doctrine also precludes, among other things, a district court’s reexamination of “an issue of law or fact decided on appeal,” which is also inapplicable here. *Gene & Gene, L.L.C. v. BioPay, L.L.C.*, 624 F.3d 698, 702 (5th Cir. 2010) (“The law of the case doctrine provides that “an issue of law or fact decided on appeal may not be reexamined either by the district court on remand or by the appellate court on a subsequent appeal.”)

<sup>5</sup> Similarly, UroPep’s reliance on cases where an expert contradicted a *legal* issue (e.g., claim construction) reinforces that UroPep’s motion *in limine* relies upon law that is simply inapplicable here. See Dkt. 205 at 4-5 (citing *Mission Pharmacal Co. v. Virtus Pharms., L.L.C.*, No. SA-13-CV-176-PM, 2014 WL 12480016, at \*3 (S.D. Tex. Sept. 12, 2014) and *Frakes v. Masden*, No. H-14-1753, 2015 WL 7583051, at \*3 (S.D. Tex. Nov. 25, 2015).

described the entire genus of PDE5 inhibitors. This point is one of the predicates for determining if the named inventors “possessed the invention that administering an effective amount of a PDE5 inhibitor would treat BPH.”

Finally, Dr. Rotella’s opinions in Paragraph 169 of his report are specifically directed to (and follow) the Court’s *legal* finding that the claims do not cover “the entire genus of PDE5 inhibitors.” Rather, as the Court held in addressing Lilly’s prior summary judgment arguments, the inventors must have possessed relevant knowledge regarding those specific *selective* PDE5 inhibitors that meet the Court’s 20-fold selectivity requirement. Whether the inventors had possession of structural features or representative examples of this different category of PDE5 inhibitors is a *factual* issue that was not presented to the Court during the prior rounds of summary judgment briefing. It must be considered by the finder of fact at trial. UroPep’s motion to strike these two paragraphs from Dr. Rotella’s testimony should be denied.

**IV. UroPep’s Fourth Motion *In Limine* Should Be Denied: UroPep’s Request To Exclude Evidence Or Argument Related To Unclean Hands Is Overstated And Unsupported**

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UroPep next seeks to exclude evidence that it contends relates to Lilly’s “Unclean Hands” defense, and specifically information relating to Dr. Ückert’s work with Lilly scientists on *Giuliano et al.*, “The Mechanism of Action of Phosphodiesterase Type 5 Inhibitors in the Treatment of Lower Urinary Tract Symptoms Related to Benign Prostatic Hyperplasia,” *European Urology* 63 (2013) 506-516 (Ex. A) (“Giuliano Article”). The Giuliano Article, however, is also relevant to Lilly’s written description and enablement defenses. Moreover, Dr. Ückert’s collaboration with Lilly scientists on the Giuliano Article, and his failure to disclose that he was actively pursuing a patent application to assert against Lilly while engaged in that collaboration, are also relevant to Dr. Ückert’s credibility and bias.

First, the Giuliano Article casts serious doubt on whether the UroPep inventors, including Dr. Ückert, had possession of the full scope of the claimed subjection matter of the ‘124 Patent in 1997. The Giuliano Article, published in 2013, indicates that researchers *still did not know* the mechanism of action regarding how certain PDE5 inhibitors treated the lower urinary tract symptoms (LUTS) associated with BPH. The Giuliano Article cites multiple alternative mechanisms of action for treatment of BPH symptoms that are inconsistent with the ‘124 Patent’s claim that relaxation of “human prostatic muscles” is the primary (or sole) mechanism for treatment. ‘124 Patent at Col. 2:6-16. The Giuliano Article instead reports that symptom relief may also be due to relaxation of smooth muscles *outside of* the prostate, increased blood perfusion, and modulation of sensory inputs. Its authors, including Dr. Ückert (one of the ‘124 Patent’s named inventors) conclude as follows:

We propose that the improvement in both storage and voiding urinary symptoms observed after 1–2 wk of tadalafil could be caused by the smooth muscle cell relaxation in bladder neck, prostate, and urethra, with the maintenance of effect possibly supported by the smooth muscle cell relaxation of these organs’ vascular supply and increased blood perfusion and oxygenation. Modulation of the sensory output from the LUT is likely to play a role in both the short and long term.

Ex. A at 514.

The fact that Dr. Ückert still did not know the mechanisms of action for treatment of the signs and symptoms of BPH *in 2013* is evidence that he and the other named inventors of the ‘124 Patent did not possess the invention of the ‘124 Patent as of its effective filing date 16 years earlier, in 1997. The Giuliano Article also casts doubt on the ‘124 Patent’s claim that relaxation of smooth muscles in the prostate via inhibition of PDE5 is the cause (or the only cause) of any symptom relief. As UroPep repeatedly relied upon the alleged insight that PDE5 was in the prostate to differentiate its purported invention from prior art references that disclosed PDE5 in

other smooth muscle tissues of the urogenital tract (the urethra, the bladder, *etc.*), it is important for the fact-finder to know that these past assertions have now been called into question by a publication that was partially authored by one of the ‘124 Patent’s named inventors.

Dr. Ückert’s failure to disclose his financial interests in the (then pending) ‘124 Patent application while collaborating on the Giuliano Article also goes directly to Dr. Ückert’s credibility as a witnesses. Dr. Ückert was willing to collaborate with Lilly and help author an article admitting that the role of PDE5 inhibitors in relieving the signs and symptoms of BPH was not fully known while at the same time privately prosecuting a patent application claiming the opposite, all with the hope of someday asserting that patent against Lilly (should it issue). The probative value of this evidence far outweighs any prejudice that UroPep may claim to suffer from a factual recitation of these events. The jury should have the complete record of the Giuliano Article when it assesses the validity of the ‘124 Patent, as well as UroPep’s claim that it is entitled to excessive damages due to Lilly’s alleged infringement.

**V. UroPep’s Fifth Motion *In Limine* Should Be Denied: Dr. Florio Will Not Offer “Expert Testimony”; He Will Authenticate And Confirm His Prior Work.**

UroPep’s fifth motion *in limine* is predicated on an incorrect assumption, *viz.*, that Lilly intends to call Dr. Florio to provide expert testimony in the lawsuit. That is not Lilly’s intention at all. Rather, Lilly may call Dr. Florio to authenticate his prior work measuring the selectivity of icariin for PDE5 as compared to other PDEs, as reflected in his pre-lawsuit declaration. His testimony will be limited to factual testimony within his personal knowledge concerning work that he performed and which is reflected in the declaration that UroPep already has. The present situation is no different from when a Court permits an inventor to testify about what he or she did in the work the led to the filing of a patent application. *See Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1339–40 (Fed. Cir. 2010) (“[T]he district court properly allowed

testimony from the witnesses about the patents they invented based on their personal knowledge, and properly excluded these same witnesses from providing expert testimony on invalidity for which they had not previously provided expert reports or been qualified as an expert.”); *Voice Techs. Grp., Inc. v. VMC Sys., Inc.*, 164 F.3d 605, 615–16 (Fed. Cir. 1999) (stating that the inventor may provide testimony explaining the claimed invention and its development, but that “the inventor cannot by later testimony change the invention and the claims from their meaning at the time the patent was drafted and granted”).<sup>6</sup>

UroPep cites two cases that it argues compel the Court to exclude Dr. Florio’s testimony regarding work he performed in the past.<sup>7</sup> These cases are either inapposite or actually favor Lilly. In *Innogenetics, N.V. v. Abbot Labs*, the District Court limited the testimony of a named inventor of a prior art PCT application to the actual words of the application. 512 F.3d 1363, 1375 (Fed. Cir. 2008). Here, Lilly seeks only to have Dr. Florio testify regarding his prior work on icariin, which is reflected in the words of the declaration he produced. This limited testimony from Dr. Florio accords with the testimony permitted in *Innogenetics* and is consistent with the cases addressing inventor testimony cited above. In UroPep’s second case, *Medtronic, Inc. v. Boston Sci. Corp.*, the Court noted that technical testimony from an employee-witness is governed by Rule 702, but it did not bar the testimony of the employee in question outright; rather, it instead required the submission of a proffer to evaluate the testimony in question. *See id.*, No. 99-1035 (RHK/FLN), 2002 WL 34447587, \*22–23 (D. Minn. Aug. 8, 2002).

This response brief serves as Lilly’s proffer on behalf of Dr. Florio. If called to testify, Dr. Florio’s testimony will be limited to his personal knowledge regarding the facts of the work

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<sup>6</sup> Moreover, if Dr. Florio were to provide expert testimony—which is not Lilly’s intent—UroPep’s motion is untimely under the Docket Control Order. Dkt. 166 at 3.

<sup>7</sup> UroPep cites a third case, *Pendarvis v. Am. Bankers Ins. Co. of Fl.*, 354 F.App’x 866 (5th Cir. 2009) for general principles applicable to expert testimony.

that he performed that is specifically documented in the Florio declaration. Lilly provided the Florio declaration to Plaintiffs in connection with its Opening Expert reports, which were timely served and which Plaintiffs do not challenge with respect to their reliance on Dr. Florio. Dr. Florio should be permitted to testify to authenticate the limited subject matter of his declaration.<sup>8</sup>

**VI. UroPep's Sixth Motion *In Limine* Is Unneeded: Neither Party Should Be Talking About Unrelated Good Works.**

Finally, Lilly agrees that neither party should be talking about their alleged “good works” that are unrelated to the lawsuit. Lilly does not intend to talk about its charitable foundation or its donations to various worthy causes, and UroPep and its named inventors also should not be testifying as to the same types of activities. This type of discussion of general (and irrelevant) “good works” is not part of the case. Both parties, however, should be permitted to explain to the jury what they do and how they do it, including their respective histories of research, discovery, and innovation. These types of activities are relevant evidence for both UroPep's claims of invention and Lilly's defenses. Lilly also must be permitted to provide testimony and evidence to educate the jury regarding the long and convoluted history of drug development, which is an integral part of (among other things) Lilly's defenses under Section 112. Lilly should be permitted to explain the investments and extensive research that it had to do in order to bring a drug like Cialis, first, to market, and then to validate and obtain Cialis's BPH indication, just as UroPep will presumably seek to introduce evidence concerning its work on PDE5 inhibitors.

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<sup>8</sup> UroPep does not challenge Dr. Roehrborn's ability to rely on Dr. Florio's declaration to support Dr. Roehrborn's expert opinions in this lawsuit.

Dated: February 17, 2017

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**CERTIFICATE OF SERVICE**

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email and/or fax, on this the 17<sup>th</sup> day of February, 2017.

/s/ Jon B. Hyland

Jon B. Hyland